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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/533,029	03/22/2000	Jacqueline Heard	MB1-0010	7823

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WILEY, REIN & FIELDING, LLP
ATTN: PATENT ADMINISTRATION
1776 K. STREET N.W.
WASHINGTON, DC 20006

EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/08/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/533,029

Applicant(s)

HEARD ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Seq Search Seq Id No 18

DETAILED ACTION

1. This Office action is in response to the Amendment and Remarks filed 29 October 2002.
2. Claims 17-36 have been cancelled without prejudice and new claims 37-76 have been added as requested.
3. The Heard Declaration filed under 37 CFR § 1.132 on 29 October 2002 has been considered and will be addressed below.
4. The information disclosure statement filed 15 October 2002 has been considered, a copy of which is attached hereto.
5. Those rejections not specifically addressed below have been withdrawn in view of Applicant's Amendments and Remarks.
6. The rejection of claims 17-36 are rejected under 35 U.S.C. § 112, second paragraph is now moot, said claims have been cancelled.
7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

8. Claims 37, 38, 40-42, 45, 46, 48-50, 53, 54, 56-58, 61, 63-68 and 70-76 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection has been modified from the rejection set forth in the last Office action mailed 29 May 2002 in view of Applicant's

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submission of new claims. Applicant's arguments filed 29 October 2002 have been fully considered but they are not persuasive.

Applicant claims a transgenic plant comprising a recombinant polynucleotide encoding a transcription factor comprising a conserved domain of a plant AP2 transcription factor wherein said transcription factor has at least 42% sequence identity with SEQ ID NO: 18, wherein said transcription factor comprises an amino acid sequence of residues 145-213 of SEQ ID NO: 18 having one or more conservative substitutions, deletions or insertions, or said polynucleotide hybridizes under ^{unspecified} stringency conditions to a polynucleotide sequence encoding an amino acid sequence of residues 145-213 of SEQ ID NO: 18, and methods of making. Applicant claims said transgenic plant and ^{a plant which} method of making has enhanced tolerance to plant disease due to changes in expression levels or activity of said transcription factor.

Applicant describes a putative AP2 transcription factor having the amino acid sequence of SEQ ID NO: 18 and encoded by a polynucleotide having the nucleotide sequence of SEQ ID NO: 17.

Applicant does not describe a transgenic plant comprising a recombinant polynucleotide encoding a transcription factor comprising a conserved domain of a plant AP2 transcription factor wherein said transcription factor has at least 42% sequence identity with SEQ ID NO: 18, wherein said transcription factor comprises an amino acid sequence of residues 145-213 of SEQ ID NO: 18 having one or more conservative substitutions, deletions or insertions, or said polynucleotide hybridizes under ^{unspecified} stringency

conditions to a polynucleotide sequence encoding an amino acid sequence of residues 145-213 of SEQ ID NO: 18, and methods of making same.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. The art teaches that plant AP2 transcription factors have diverse functions and that one of skill in the art cannot recognize correlation or relationship between the structure and the specific function a plant AP2 transcription factor. In particular the precise function of plant AP2/EREBP transcription factors, which appear to be involved in response to

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biotic and environmental stress, was unknown at the time of Applicant's invention, hence one of skill in the art at the time of Applicant's invention could not have correlated precise function with the structure of an encoded AP2 transcription factor (see Riechmann and Meyerowitz 1998, Biol. Chem. 379:633-646, especially the Abstract on page 633 and page 639, right column, 3rd paragraph).

Applicant argues that the Heard Declaration demonstrates and subsequent publications demonstrate that SEQ ID NO: 18 is a transcription factor (pages 21-22 of the Remarks). The Examiner accepts the argument, those claims directed to transgenic plants comprising a recombinant protein having the amino acid sequence of SEQ ID NO: 18 are not included in the instant rejection. The Examiner notes the statement in the Heard Declaration at item 7 as evidence.

Applicant argues that ^{as} one of ordinary skill in the art recognizes, conserved domains may be identified as regions or domains of identity to a specific consensus ^{sequence} and that by using alignment methods well known in the art, the conserved domains of the AP2 domain transcription factor, the function of the presently claimed transcription factors may be determined family [sic]. Applicant also argues that at the time the present application was filed, one of skill in the art would recognize that portions of the AP2 domain are absolutely conserved and that AP2 transcription factors are distinguishable by differential DNA-binding specificities (pages 24 and 25 of the Remarks). The Examiner does not argue that one of skill in the art at the time of Applicant's invention would ^{not} inherently recognize a polypeptide sequence as having an AP2-like domain and would ^{not} speculate that said polypeptide sequence is a transcription

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factor, but one of skill in the art at the time of Applicant's invention could not inherently recognize what the AP2-like transcription factor regulates in a plant simply based on the structure of the polypeptide.

Applicant argues that one of skill in the art would not doubt that Applicants have adequately described the recited polynucleotides, specified a novel and useful transcription factor function of G28 and other AP2 family transcription factors in plants, and demonstrated that they can be made and used to enhance plant disease tolerance (page 26, 2nd paragraph of the Remarks). The Examiner has addressed the argument above. The Examiner notes that the instant rejection is not directed to the utility of the claimed invention, just to whether Applicant has adequately described the claimed genus of transgenic plant and isolated polynucleotides used to make said transgenic plants as broadly claimed.

9. Claims 37-76 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection has been modified from that set forth in the last Office action mailed 29 May 2002 in view of Applicant's submission of new claims and the Heard Declaration. Applicant's arguments filed 29 October 2002 have been fully considered but they are not persuasive.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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In the instant case Applicant, at the time of the instant invention, failed to enable any person of skill in the art to which it pertains, or with which it is most nearly connected, to use the invention. The instant specification provides no guidance to one of skill in the art as to what specific function a polypeptide having the amino acid sequence shown in SEQ ID NO: 18 has, or how to use a transgenic plant comprising a recombinant polynucleotide encoding said polypeptide as claimed. Nor does the instant specification enable one of skill in the art at the time of the invention to practice a method of altering the expression levels of at least one gene in a plant wherein said plant has enhanced tolerance to plant disease due to changes in expression levels or activity of a transcription factor having the amino acid sequence of SEQ ID NO: 18. The art teaches that the precise function of plant AP2/EREBP transcription factors, which appear to be involved in response to biotic and environmental stress, was unknown at the time of Applicant's invention, hence one of skill in the art at the time of Applicant's invention could not have correlated precise function with the structure of an encoded AP2 transcription factor (see Riechmann and Meyerowitz 1998, Biol. Chem. 379:633-646, especially the Abstract on page 633 and page 639, right column, 3rd paragraph). In addition, claims directed to transgenic plants comprising recombinant polynucleotides encoding transcription factors having at least 42% sequence identity with the AP2 transcription factor of SEQ ID NO: 18, polynucleotide ^s that hybridize ^{low or moderately} under stringent conditions or that have one or more conserved substitutions, deletions or insertions at residues 145-231 of SEQ ID NO: 18, and are capable of conferring enhanced tolerance to plant disease on a transgenic plant, are not enabled as broadly claimed.

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Applicant argues that the Heard Declaration demonstrates that a transcription factor having the amino acid sequence of SEQ ID NO: 18 confers pathogen or disease tolerance on a transgenic plant as claimed (page 26, 5th paragraph of the Remarks). The Examiner has noted the evidence, but the issue remains that Applicant did not teach one of skill in the art how to use a transgenic plant transformed with a polynucleotide encoding the polypeptide shown in SEQ ID NO: 18 at the time of the invention. The Examiner refers to original claim 17 (now cancelled) that lists multiple traits, including pathogen stress, and that original claim 22 (now cancelled) is directed to a transgenic plant wherein the [nucleotide sequence] polypeptide is SEQ ID NO: 18 and confers tolerance to salt, heat, drought, osmotic stress, cold, freezing, or nutrient or pathogen stress. Hence, Applicant failed to teach one of skill in the art at the time of the invention how to use a transgenic plant transformed to express a polypeptide having the amino acid sequence of SEQ ID NO: 18 to enhance tolerance to plant disease as claimed.

Applicant argues that Quattrocchio 1998 does not support an argument of undue trial and error experimentation, but that Quattrocchio strongly suggests the very opposite. Applicant argues that in the Heard Declaration, Dr. Heard argues that the teachings of Quattrocchio actually supports the predictable nature of using transcription factors to produce predictable effects on the same traits in plants (page 26, 4th paragraph to page 28, 3rd paragraph of the Remarks). This argument is not found to be fully persuasive because Quattrocchio also teaches that one would expect *jaf13* or *delila* to activate all structural anthocyanin genes of *Z. mays*, however neither could

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complement an *r* mutation. Quattrocchio further speculates that *jaf13* and *delila* failed to complement the *Z. mays* mutation due to poor interaction with some unknown factor in the ^{pathway} required to produce the predicted phenotype (page 486, left column, 2nd paragraph).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 37, 38, 40-42, 45, 46, 48-50, 53, 54, 56-58, 61, 63-68 and 70-76 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zhou *et al* 1997 (The EMBO Journal 16(11):3207-3218).

Zhou teaches an AP2-like transcription factor encoding polynucleotide that encodes a polypeptide that is 42.2% identical to Applicant's SEQ ID NO: 18 (see Fig. 2B, Pti4, on page 3209). Zhou teaches that the Pti4 transcription factor regulates expression of PR proteins in tomato, said PR proteins known to confer disease resistance in plant (see Abstract on page 3207 and Fig. 8 on page 3214). The amino acid sequence taught by Zhou in the Pti4 polypeptide comprises residues 145-213 of Applicant's SEQ ID NO: 18, having one or more conservative substitutions, deletions, or insertions.

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Zhou does not specifically teach transgenic plants transformed with the taught Pti4 transcription factor gene or a method of enhancing the disease tolerance or resistance of a plant comprising said gene.

Zhou does teach that the discovery of Pti4 as PR box-binding factors may provide a new approach to improving crop plants with enhanced PR gene expression and disease resistance because it would be more effective to engineer crop plants with enhanced protection against pathogens by coordinately expressing a large combination of PR proteins in the plant (page 3214, left column, 3rd paragraph).

Hence, it would have been *prima face* obvious to one of ordinary skill in the art at the time of Applicant's invention to make a transgenic plant using the Pti4 gene taught by Zhou to enhance the disease tolerance or resistance of said transgenic plant compared to a non-transformed plant. Given that Zhou teaches that the Pti4 transcription factor regulates expression of a large number of PR proteins, said PR proteins known in the art to enhance disease tolerance or resistance in plant, one of ordinary skill in the art at the time of Applicant's invention would have had a reasonable expectation of success in enhancing the disease tolerance or resistance in a transgenic tomato plant by overexpressing the Pti4 transcription factor taught by Zhou.

Double Patenting

12. Claims 37-76 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 09/713,994. Although the conflicting claims are not identical, they are not patentably distinct from each other because SEQ ID NO: 17 of the instant

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application is identical to SEQ ID NO: 28 of the copending application. Any claims to transformed plants of the copending application would inherently have the claimed phenotype of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This rejection is repeated for the reason of record in the last Office action mailed 29 May 2002. Applicant's statement that Applicants will address this rejection when claims of this or the copending application are allowed is noted by the Examiner (page 28, last paragraph of the Remarks).

13. Claims 37-76 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 09/934,455. Although the conflicting claims are not identical, they are not patentably distinct from each other because SEQ ID NO: 17 of the instant application is identical to SEQ ID NO: 32 of the copending application. Any claims to transformed plants of the copending application would inherently have the claimed phenotype of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This rejection is repeated for the reason of record in the last Office action mailed 29 May 2002. Applicant's statement that Applicants will address this rejection when claims of this or the copending application are allowed is noted by the Examiner (page 28, last paragraph of the Remarks).

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

15. No claims are allowed.

16. Claims 39, 43, 44, 47, 51, 52, 55, 59, 60, 62 and 69 appear to be free of the prior art which neither teaches nor fairly suggests a transgenic plant transformed with a polynucleotide encoding the amino acid sequence of SEQ ID NO: 18 wherein said polynucleotide enhances tolerance to plant disease.

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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

David H. Kruse, Ph.D.
2 January 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180

David T. Fox